



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-16-1067]**

**[Docket No. CDC-2015-0106]**

**Proposed Data Collection Submitted for Public Comment and  
Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS)

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision of the information collection entitled *Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics - College of American Pathologists*, which will allow for a fuller exploration of the factors that underlie the reasons why

laboratorians adhere to the College of American Pathologists' laboratory practice guideline for immunohistochemistry test validation.

**DATES:** Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0106 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on

the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed

collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

### **Proposed Project**

Improving the Impact of Laboratory Practice Guidelines (LPGs): A New Paradigm for Metrics - College of American Pathologists, REVISION (OMB Control No. 0920-1067, Expiration 05/31/16) - Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

## **Background and Brief Description**

The Centers for Disease Control and Prevention is funding three 5-year projects collectively entitled "Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics". An "LPG" is defined as written recommendations for voluntary, standardized approaches for medical laboratory testing that takes into account processes for test selection, sample procurement and processing, analytical methods, and results reporting for effective diagnosis and management of disease and health conditions. LPGs may be disseminated to, and used by, laboratorians and clinicians to assist with test selection and test result interpretation. The overall purpose of these cooperative agreements is to increase the effectiveness of LPGs by defining measures and collecting information to inform better LPG creation, revision, dissemination, promotion, uptake, and impact on clinical testing and public health. The project will explore how these processes and their impediments and facilitators differ among various intended users of LPGs. Through this demonstration project, CDC seeks to understand how to customize LPG creation and promotion to better serve these intended users of LPGs. An important goal is to help organizations that sponsor the development of LPGs create a sustainable approach for continuous quality improvement to

evaluate and improve an LPG's impact through better collection of information.

The CDC selected three organizations that currently create and disseminate LPGs to support activities under a cooperative agreement funding mechanism to improve the impact of their LPGs. The American Society for Microbiology, the Clinical and Laboratory Standards Institute, and the College of American Pathologists (CAP), will each use their LPGs as models to better understand how to improve uptake and impact of these and future LPGs. Only the CAP submission will be described in this notice.

The CAP project will address two LPGs that are important to clinical testing: immunohistochemistry test validation (IHC) and an algorithm for diagnosing acute leukemia (ALA). As part of the completed survey collections that was conducted under OMB Control Number 0920-1067, the intended users of the CAP's IHC LPG included pathologists, clinical laboratory directors, and laboratory managers overseeing the IHC staining department; the intended users of the CAP's ALA LPG were pathologists and hematologists overseeing testing for acute leukemia. For this revision request, CDC is proposing information collections to conduct qualitative studies of the survey respondents of the IHC post-survey with the intent to include representation from the

laboratory professionals who submitted the IHC post-survey results (pathologists, clinical laboratory directors, and laboratory managers).

Prior to entering into this cooperative agreement project with the CDC, the CAP had already completed a baseline IHC LPG information collection from laboratories that used IHC testing. Because of this prior baseline assessment, the CAP only needed to collect post-dissemination data. This has been completed using the information approved under OMB Control Number 0920-1067. Similarly, the CAP also completed an ALA baseline survey under this clearance.

We are submitting a revision request to allow for a fuller exploration of the factors that underlie the reasons why laboratorians adhere to the College of American Pathologists' laboratory practice guideline for IHC. We propose to conduct telephone interviews that will explore the impediments and facilitators that affect uptake and use of the CAP IHC LPG, both generally and concerning specific recommendations. This will be followed by two focus groups, arranged by peer group of pathologists and non-pathologists (referred to as laboratory directors and managers for the purpose of estimating burden), which will allow us to collect information on the current usage of CAP's tools and resources (toolkit) to facilitate

implementation of the IHC guideline for its future improvement. To the extent possible, we will include non-adopters of the CAP's IHC LPG, but this fraction won't be known until the information collection occurs. We propose to collect information for the telephone interviews and focus groups combined, from 64 of the IHC post-survey respondents which include pathologists and non-pathologist laboratory directors and laboratory managers.

For this request, the CAP will collect information via telephone interviews from 40 laboratorians. The time it will take each respondent to complete the interview is 20 minutes. Because the CAP anticipates that as many as 121 individuals may need to be contacted to reach 40 individuals who will voluntarily participate, and the burden for those individuals who will not go on to participate (81) in the telephone interview is one minute, the anticipated total burden for individuals who decline participation is 1.35 hours (81 minutes). The telephone interview respondents will be targeted from two primary segments: (1) laboratories exclusively using CAP Proficiency Testing (PT) products, and (2) laboratories identified by Centers for Medicare and Medicaid Services billing codes that perform IHC testing but are not enrolled in CAP PT products. The telephone interview respondents will be randomly

sampled from the submitted post-survey results and will be cross-checked for appropriate distribution of laboratory type and size. Because there are fewer of them, all of the non-CAP PT customer respondents will be included. The CAP estimates that the individuals who complete the telephone interview will be comprised of 20 pathologists, 10 laboratory directors, and 10 laboratory managers and will each take 20 minutes and the 40 respondents combined will take approximately 13 hours (800 minutes) total burden.

The two in-person focus group sessions will include some of the probe questions from the telephone interview survey and a specific subset concentrating on evaluating CAP's current tools and resources (toolkit). It is anticipated that 200 individuals will be contacted to determine their availability to participate in one of two focus group sessions and each will take no longer than five minutes to read and respond to the invitation letter (~17 hours or 1,000 minutes total). Among the 200 individuals contacted, only the 24 who are selected to participate in a focus group session will each be asked to read and submit a signed consent form prior to the session (5 minutes each) (2 hours or 120 minutes total). Twelve participants will be selected to participate in each of the two focus groups (pathologist peers and laboratory director/manager peers) and

will last no more than 90 minutes each (36 hours or 2,160 minutes total). Thus, the total burden for the focus group is estimated to be ~55 hours (3,280 minutes) total.

Including both telephone interviews and focus group sessions, the total new burden for this revision request will be an additional ~68 hours (321 individuals) at \$4,421 total, compared with the original OMB approved burden of 1,570 hours (4,435 individuals) at \$97,460 total.

There are no costs to respondents other than their time.

#### Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Pathologist	IHC telephone interview	20	1	20/60	7
	IHC telephone interview-contacted	27	1	1/60	0.45
	IHC focus group	12	1	1.50	18
	IHC focus group-invitation	100	1	5/60	8

	IHC focus group-consent form	12	1	5/60	1
Laboratory Directors	IHC telephone interview	10	1	20/60	3
	IHC telephone interview-interviewed	27	1	1/60	0.45
	IHC focus group	6	1	1.50	9
	IHC focus group-invitation	50	1	5/60	4
	IHC focus group-consent form	6	1	5/60	0.50
Laboratory Managers	IHC telephone interview	10	1	20/60	3
	IHC telephone interview-interviewed	27	1	1/60	0.45
	IHC focus group	6	1	1.50	9
	IHC focus group-invitation	50	1	5/60	4
	IHC focus group-consent form	6	1	5/60	0.50
Total					68.00

Leroy A. Richardson  
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 Office of Scientific Integrity  
 Office of the Associate Director for Science  
 Office of the Director  
 Centers for Disease Control and Prevention

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